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BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			FREDMAN, JEFFREY NORMAN	
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			1634	
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Please find below and/or attached an Office communication concerning this application or proceeding.

37.

8/12

<b>Office Action Summary</b>	<b>Application No.</b> 09/935,592	<b>Applicant(s)</b> HAYASHIZAKI, YOSHIHIDE	
	<b>Examiner</b> Jeffrey Fredman	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8-25, 27-40, 42-86, 89 and 90 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-25, 27-40, 42-86, 89 and 90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \*   c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. Claims 1-6, 8-21, 74 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "cDNAs characterized by comprising the steps of" is unclear. This phrase is indefinite since it is unclear what "characterizes" the cDNAs with regard to the steps. Deletion of the phrase "characterized by" would overcome this rejection.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-4, 6, 8-23, 25, 27-40, 42-73, 77-86 are rejected under 35 U.S.C. 102(a) as being anticipated by Carninci et al (Genome Research (October 2000) 10:1617-1630).

Carninci (Genome Research) teaches a method of preparing normalized and/or subtracted cDNAs (see abstract) comprising the steps of:

I) preparing uncloned single stranded cDNAs by reverse transcription of mRNA in the form of uncloned cDNA (see figure 1 and page 1625-1626, subheading "cDNA synthesis"),

II) preparing polynucleotides (drivers) for normalization and/or subtraction, including the use of RNA drivers (see figure 1 and page 1627, column 2, subheading "normalization drivers")

III) conducting normalization and/or subtraction and removing tester/driver hybrids and non-hybridized polynucleotide drivers where normalization occurs either prior to or at the same time as subtraction (see figure 1 and page 1628, column 1, subheadings "Normalization/subtraction" and "removal of the hybrid"); and

IV) recovering the normalized and/or subtracted CDNA (see figure 1 and page 1628, column 2).

Carninci (Genome Research) teaches that the cDNA is full length (see page 1621, column 1). Carninci (Genome Research) teaches the addition of RNase I to remove the RNA driver from step III (see page 1628, column 2 and subheading

"Removal of the hybrid"). Carninci (Genome Research) teaches cap trapping of the cDNA tester by interacting a diol group with a biotin label (see page 1626, column 2). Carninci (Genome Research) teaches the use of normalization and subtraction drivers where the driver is either mRNA or cDNA (see figure 1) which is either the same or different from the population to be subtracted and normalized (see table 1, figure 1 and page 1621).

Carninci (Genome Research) teaches cloning the recovered cDNA (see page 1628, column 2, subheading "cDNA cloning"). Carninci (Genome Research) teaches removal of the hybrids using magnetic beads (see figure 1).

4. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

5. The rejection of claims 1-3, 6, 7, 15-22, 25, 26, 32-41 and 49-55 under 35 U.S.C. 102(e) as being anticipated by Chang (U.S. Patent 6,143,874) is withdrawn in view of the amendment.

6. The rejection of claims 1-7, 15-18, 21-26, 32, 33, 36-41, 50-52, 55 under 35 U.S.C. 102(b) as being anticipated by Ruppert (U.S. Patent 5,891,637) is withdrawn in view of the amendment.

7. Claims 77-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Carninci et al (Genomics (1996) 37:327-336).

Carninci (Genomics) teaches a method of isolating single strand cDNA comprising the steps of treating a hybrid comprising RNA nonspecifically bound to

cDNA with RNase I, which is an enzyme capable of degrading single strand RNA (see page 330, column 2, subheading "RNase I protection of full length cDNA and figure 1), removing the degraded single stranded RNA (See page 331, column 1, subheading "capture of full length cDNA" and figure 1), and recovering the cDNA (see page 331, column 1, subheading "capture of full length cDNA" and figure 1). Carninci (Genomics) teaches that the resultant cDNA will be full length (See page 330, column 2). Carninci (Genomics) then teaches formation of a library with the full length cDNAs in the Lambda ZAP II vector (see page 331, column 1, especially subheading "Second-strand cDNA synthesis and Cloning). Since the hybridization step is inherently a form of normalization/subtraction, Carninci (Genomics) inherently teaches such a step (see figure 1).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-6, 8-25, 27-40, 42-73, 77-86, 89, 90 are rejected under 35 U.S.C.

103(a) as being unpatentable over Chang (U.S. Patent 6,143,874) in view of Carninci et al (Genomics (1996) 37:327-336).

Chang teaches a method of preparing normalized and/or subtracted cDNAs (see abstract) comprising the steps of:

I) preparing uncloned single stranded cDNAs by reverse transcription of mRNA in the form of uncloned cDNA (see column 24, lines 34-54),

II) preparing polynucleotides (drivers) for normalization and/or subtraction, including the use of RNA drivers (see column 24, lines 55-61)

III) conducting normalization and/or subtraction and removing tester/driver hybrids and non-hybridized polynucleotide drivers where subtraction and normalization occur simultaneously (see column 24, line 62 to column 25, line 18); and

IV) recovering the normalized and/or subtracted CDNA (see column 25, lines 5-10).

Chang teaches that the tester was single stranded (see column 24, lines 52-54). Chang teaches cloning the recovered cDNA into a vector (see column 25, lines 20-24). Chang teaches that at least some of the cDNAs are full length (see column 25, line 40). Chang teaches a normalization/subtraction driver from the same tissue which has been differently treated for the normalization, resulting in a different population of cDNAs, thereby meeting both the same tissue requirement and the different cDNA population requirements (see column 23, line 60 to column 24, line 11). Chang teaches removal using the biotin/streptavidin system (see column 25).

Chang teaches a desire to remove residual single stranded mRNA (see column 24, lines 42-43) but does not teach use of an enzyme. Chang also teaches that full length clones are desired (see column 25, lines 35-38, also see column 8), but Chang does not teach a protocol to ensure that full length clones are synthesized.

Carninci (Genomics) teaches a method of isolating full length single strand cDNA comprising the steps of

(1) chemically binding a biotin tag to the diol structure of the 5' cap site of mRNA (see page 329, subheading "biotinylation of Diol groups of RNA),

(2) synthesizing first strand cDNA by means of reverse transcriptase to from mRNA/cDNA hybrids (see page 329, subheading "First strand cDNA synthesis"),

(3) treating the hybrid comprising RNA nonspecifically bound to cDNA (and RNA specifically bound to the cDNA) with RNase I, which is an enzyme capable of degrading single strand RNA (see page 330, column 2, subheading "RNase I protection of full length cDNA and figure 1), removing the degraded single stranded RNA (See page 331, column 1, subheading "capture of full length cDNA" and figure 1), and recovering the cDNA using streptavidin coated magnetic beads (see page 328, column 2 and page 331, column 1, subheading "capture of full length cDNA" and figure 1). Carninci (Genomics) teaches that the resultant cDNA will be full length (See page 330, column 2). Carninci (Genomics) then teaches formation of a library with the full length cDNAs in the Lambda ZAP II vector (see page 331, column 1, especially subheading "Second-strand cDNA synthesis and Cloning). Carninci (Genomics) performs the biotinylation on ice (see page 328, column 2).

With regard to the  $R_0T$  value of claim 89 of from 5 to 10, this value is based upon the nucleic acid population being measured, not upon the method of analysis.

Consequently, since the claims are open to any nucleic acid population, the nucleic acid populations taught by Chang and Carninci will necessarily meet this requirement.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Chang by using the biotin tag on the 5' cap site and RNase I digestion method of Carninci in order to achieve the goals of Chang in removing residual single stranded mRNA and in obtaining full length cDNA clones since Chang expressly teaches that "We have devised a method for efficiently constructing high-content full-length cDNA libraries based on chemical introduction of a biotin group into the diol residue of the cap structure of eukaryotic mRNA, followed by RNase I treatment to select full-length cDNA. The selection occurs by trapping the biotin residue at the cap sites using streptavidin-coated magnetic beads, thus eliminating incompletely synthesized cDNAs (abstract)." Thus, an ordinary practitioner would have been motivated to modify the cDNA preparation method of Chang to use the method of Carninci in order to efficiently achieve full length, rather than truncated, cDNAs, thereby maximizing the accuracy and usefulness of the resulting cDNA.

Further, with regard to the order of the steps, either in the normalization/subtraction context or in the tagging and cDNA synthesis context, the alteration in order is prima facie obvious since the claim is of the open "comprising" format, which permits rearrangement of the method steps. Further, as MPEP 2144.04 notes "selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results". Here, the order of the steps is reversed in some of the claims, but changing the order of steps is obvious in the absence of secondary considerations. This is particularly the case in subtraction/normalization type reactions, where the ordinary practitioner would have recognized that the method would

work whether a subtraction was followed by normalization or the reverse, with the only difference being the level of normalization or subtraction desired.

10. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (U.S. Patent 6,143,874) in view of Carninci et al (Genomics (1996) 37:327-336) as applied to claims 1-6, 8-25, 27-40, 42-73, 77-86, 89 and 90 and further in view of Bouma et al (U.S. Patent 5,585,242).

Chang in view of Carninci (Genomics) teach the limitations of claims 1-6, 8-25, 27-40, 42-73, 77-86, 89 and 90 as discussed above. Chang in view of Carninci (Genomics) specifically teach capture using the biotin streptavidin interaction. Chang in view of Carninci (Genomics) do not teach the use of the equivalent capture method of biotin and an anti-biotin antibody.

Bouma teaches that avidin and anti-biotin antibodies are equivalent capture modes for biotin labeled moieties (see column 13, lines 15-20).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute the known equivalent of anti-biotin antibodies for avidin into the method of Chang in view of Carninci (Genomics) since the MPEP notes that such substitutions are obvious. As MPEP 2144.06 notes " Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such

substitution obvious. In re Fout , 675 F.2d 297, 213 USPQ 532 (CCPA 1982).” Here, the equivalency of avidin and antibiotin antibodies is expressly recognized by Bouma, who cites them as equivalents (See column 13, lines 15-20).

11. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (U.S. Patent 6,143,874) in view of Carninci et al (Genomics (1996) 37:327-336) and further in view of Mishra et al (U.S. Patent 5,955,954).

Chang in view of Carninci (Genomics) teach the limitations of claims 1-6, 8-25, 27-40, 42-73, 77-86, 89 and 90 as discussed above. Chang in view of Carninci (Genomics) specifically teach capture using the biotin streptavidin interaction. Chang in view of Carninci (Genomics) do not teach subtraction using streptavidin/phenol extraction.

Mishra teaches subtraction using streptavidin/phenol extraction (see column 27, lines 38-43).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Chang in view of Carninci (Genomics) to use the streptavidin/phenol extraction method of Mishra since Chang in view of Carninci (Genomics) expressly desires removal of the highly abundant RNAs (see page 331, column 1 of Carninci, for example) and Mishra teaches an efficient way to perform subtraction, by “streptavidin-phenol extraction: the streptavidin -biotin hybrid duplexes represent common gene products which selectively partition into the phenol interface, leaving the unique, subtracted single stranded cDNA in the aqueous phase (see column 27, lines 40-43)”. Thus, an ordinary practitioner would have been

motivated to use the streptavidin/phenol method of Mishra since this is an efficient way to subtract. The combination of the Mishra technique being with the streptavidin capture would provide an increase in the sensitivity and specificity of the combined assay because the combination would remove more of the undesirable RNA.

12. Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (U.S. Patent 6,143,874) in view of Carninci et al (Genomics (1996) 37:327-336) as applied to claims 1-6, 8-25, 27-40, 42-73, 77-86, 89 and 90 and further in view of Lavery et al (U.S. Patent 6,090,548).

Chang in view of Carninci (Genomics) teach the limitations of claims 1-6, 8-25, 27-40, 42-73, 77-86, 89 and 90 as discussed above. Chang in view of Carninci (Genomics) specifically teach capture using the biotin streptavidin interaction. Chang in view of Carninci (Genomics) do not teach the use of the equivalent capture method of hydroxyapatite column.

Lavery teaches that avidin/biotin and hydroxyapatite columns are equivalent capture modes for desired cDNA in subtraction methods such as those of Chang and Carninci (see column 2 lines 6-9).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute the known equivalent of hydroxyapatite columns for avidin/biotin system into the method of Chang in view of Carninci (Genomics) since the MPEP notes that such substitutions are obvious. As MPEP 2144.06 notes " Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency

must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout , 675 F.2d 297, 213 USPQ 532 (CCPA 1982).” Here, the equivalency of avidin/biotin and hydroxyapatite columns is expressly recognized by Lavery, who cites them as equivalents (See column 2, lines 6-9).

### ***Response to Arguments***

13. Applicant's arguments filed October 1, 2003 have been fully considered but they are not persuasive.

Applicant states that the term “characterized by” was deleted. It was deleted in claim 22, so the rejection is withdrawn over that claim, but the phrase remains in claim 1, so the rejection over that claim is maintained.

Applicant first argues that the 102(a) over Carninci (2000) should be withdrawn because Applicant will file a verified English translation. No such translation was filed.

Applicant then argues that the 102(e) over Chang et al should be withdrawn because Chang does not teach “full length” cDNA. As noted in the 103 rejection, Chang desires full length cDNA, and Chang obtained, in at least one experiment, full length cDNA. However, Applicant is correct that Chang's method does not appear to reliably form full length cDNA and therefore, the 102(e) rejection over Chang alone is withdrawn in view of the amendment.

Applicant then argues the 102(b) over Ruppert, trying to distinguish tester and driver. Applicant is applying labels to products, where the label lacks significance. However, a more significant issue is that example 1 of Ruppert expressly indicates that full length clones are not necessary for the method, thus teaching away from the claimed invention.

Applicant then argues the 102(b) over Carninci (1996) by stating that the RNAs being cleaved are not "nonspecifically bound". This argument is not persuasive for several reasons. First, Carninci is performing the same steps as Applicant for the same purpose with the same enzymes. Consequently, the results must be the same. Second, and more importantly, the RNAs of Carninci which are degraded are, by definition, not specifically bound to DNA or the RNase enzyme could not degrade them. As Carninci states "mRNA hybridized with full-length cDNA is completely protected from RNase I digestion, but mRNA hybridized to partially synthesized cDNA exposes the single-stranded RNA sequence to attack by RNase I. (see page 330, column 2)." Thus, only unhybridized RNA is cleaved and that unhybridized portion is not specifically bound to any other nucleic acid. Therefore, the teachings of Carninci (1996) meet the current claim limitations.

Applicant then argues the 103 rejection. Applicant relies upon the arguments against Chang previously regarding the tester and driver. However, the issue is not the terms used, but what actually occurs. The claim requires that full length cDNA be made, other nucleic acids be prepared, mixing the two sets of nucleic acids, and recovering the full length cDNAs. Which nucleic acid is termed "tester" and which is termed "driver" is

not relevant, since the names do not control, only the actual steps of the claims with actual limitations. In fact, however, Chang uses the correct terms and uses them in the same way as Applicant's claims. A review of the reference at columns 24 and 25 makes it clear that Chang performs the step of making cDNA tester (see column 24, lines 33-54), mRNA driver (see column 24, lines 55-61), and performs a subtraction (see column 24, line 62, "subtractive hybridization reaction" to column 25, line 18) where the driver is removed (see column 25, lines 1-18) and the cDNA is recovered (see column 25, lines 1-18). Chang teaches and suggests the desirability of these steps. The motivation to remove the non specific RNA material is also expressly provided by Chang who teaches removal of non specific RNA from the driver (see column 24, lines 40-41) and by Carninci (1996) who teaches that such removal is desired (see, for example, abstract).

The rejection over Ruppert is rewritten, based upon the amendment, to be based upon Chang in view of Carninci. This new rejection was necessitated by Applicant's amendment.

The remaining arguments depend upon overcoming the base rejection. Because that argument was not persuasive, neither are these arguments.

### ***Conclusion***


14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is currently 703-308-6568. In mid January, 2004, when TC 1600 relocates to the new USPTO facility in Alexandria, the examiner's phone number will become 571-272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The supervisor's new telephone number in mid January will be 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is currently 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman  
Primary Examiner  
Art Unit 1634